

Remarks/Arguments:

Introduction

Claims 1-15, 18, 19, 21 and 36-40 are pending. Claims 16, 17 and 22-35 are canceled. Claims 36-40 have been added

Claim 1 has been amended to describe the inflation medium as comprising a curable liquid. Support for this claim amendment may be found in originally filed claim 17. Claim 36 has been added. Support for newly added claim 36 may be found in originally filed claim 17. Claim 37 has been added. Support for newly added claim 37 may be found in originally filed claim 15. Claims 38 and 40 have been added. Support for newly added claims 38 and 40 may be found in the specification at paragraph [0022] at page 8, lines 28-30. Claim 39 has been added. Support for newly added claim 39 may be found in the specification at paragraph [0022] at page 8, lines 28-30, and in originally filed claim 1.

No new matter is introduced with these amendments.

Summary of Independent Claims

The invention as presently defined by independent claim 1 is directed to a graft. The graft of this aspect of the invention comprises a graft body section having a proximal end, a distal end, and defining at least one inflatable porous channel; at least one inflatable porous cuff disposed at the proximal or distal end of the graft body section and in fluid communication with the at least one channel; and an inflation medium including at least one therapeutic agent configured to be introduced into the inflatable channel; wherein the inflation medium comprises a curable liquid. (emphasis added)

The invention as presently defined by independent claim 21 is directed to a graft. The graft of this aspect of the invention comprises a graft body section having a proximal end, a distal end, and defining at least one inflatable porous channel therebetween; a connector member affixed to the proximal or distal end of the graft body section, the connector member

comprising one or more connector elements; a stent comprising one more proximal stent connector elements coupled to the one or more connector member connector elements; and an inflation medium including at least one therapeutic agent configured to be introduced into the inflatable channel. (emphasis added)

The invention as presently defined by independent claim 39 is directed to a graft. The graft of this aspect of the invention comprises a graft body section having a proximal end, a distal end, and defining at least one inflatable porous channel; at least one inflatable porous cuff disposed at the proximal or distal end of the graft body section and in fluid communication with the at least one channel; and an inflation medium including at least one therapeutic agent configured to be introduced into the inflatable channel; wherein the inflation medium comprises a curable liquid; and wherein the curable liquid is selected from the group consisting of polyethylene glycol diacrylate, ethoxylated trimethylolpropane triacrylate, or polypropylene glycol diacrylate in combination with pentaerythritol tetra 3 (mercaptopropionate).

Section 103 Rejections

A. Claims 1-9, 16, 19 and 21 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over U.S. Patent Application Publication No. 2002/0103527 to Kocur et al. (hereinafter "Kocur") in view of U.S. Patent Application No. 2002/0091440 to Calcote (hereinafter "Calcote"). Applicants respectfully traverse.

With respect to independent claim 21, Kocur and Calcote, individually or in combination, clearly fail to teach or suggest, *inter alia*, a connector member affixed to the proximal or distal end of the graft body section and a stent comprising one more proximal stent connector elements coupled to the one or more connector member connector elements. Indeed, Calcote fails to teach or suggest the use of a stent with its graft device. Kocur teaches the use of a stent with its graft, but fails to teach or suggest a connector member affixed to the proximal or distal end of its graft and a stent coupled to the so affixed connector member.

Thus, applicants respectfully request withdrawal of the finality of the action's rejections because, *inter alia*, Kocur and Calcote, individually or in combination, clearly fail to teach or suggest the connector member and the stent as recited by independent claim 21. Therefore, reconsideration and withdrawal of the rejection of claim 21 is respectfully requested.

With respect to independent claim 1, Kocur and Calcote, individually or in combination, clearly fail to teach or suggest, *inter alia*, an inflation medium where the inflation medium comprises a curable liquid. Therefore, reconsideration and withdrawal of the rejection of claim 1 is respectfully requested.

B. Claims 10, 12-15 and 18 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kocur in view of Calcote and in further view of U.S. Patent No. 6,051,648 to Rhee et al. (hereinafter "Rhee"). Applicants respectfully traverse.

Rhee is directed to "crosslinked polymer compositions ... as bioadhesives ... and as drug delivery matrices...." (Rhee, column 1, lines 13-21). The compositions of Rhee are "not readily degradable in vivo...." (Rhee, column 3, line 60). The bioadhesives are specifically formulated for "effecting temporary or permanent attachment between the surfaces of two native tissues, or between a native tissue surface and a non-native tissue surface or a surface of a synthetic implant. (Rhee, column 16, lines 64-67). "Synthetic implants [may] include vascular grafts, stents, and stent/graft combinations...." (Rhee, column 18, lines 18-21).

Rhee, however, fails to teach or suggest that its compositions may be used within an inflatable channel of a graft. Indeed, Rhee specifically teaches that its compositions are to be used at at least one native tissue surface. (Rhee, column 16, lines 64-67). Thus, Rhee fails to teach or suggest that its compositions may be used within the inflatable channel of the graft as presently set forth in independent claim 1. Moreover, in direct contrast to the limitations of claim 12, Rhee teaches that its compositions "not readily degradable in vivo...." (Rhee, column 3, line 60).

Further, one of ordinary skill in the art would not be motivated to combine Kocur, Calcote and Rhee in any attempt to arrive at the present invention. For example, Calcote requires that its conduits on its graft be open C-shaped conduits or perforated conduits to allow release of a therapeutic agent toward the graft wall. (Calcote, paragraph [0024]). The use of the curable compositions of Rhee would seal such open portions or perforations of Calcote, thereby destroying the intent, purpose and functionality of the conduits of Calcote.

It is incumbent upon the Examiner to provide a reason why one of ordinary skill in the art would have been led to modify the specific teachings of Calcote and to combine Calcote with Kocur and Rhee to arrive at the claimed invention. The requisite motivation for relying upon the cited references and making the proposed combination must reference some teaching, suggestion or inference in the prior art as a whole, or from the knowledge generally available to one of ordinary skill in the art and not from Applicants' disclosure. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). The only possible motivation to combine and modify these references is the teachings of the subject application. Such hindsight reconstruction, however, is strictly prohibited.

Thus, applicants respectfully submit that Kocur, Calcote and Rhee, individually or in combination, fail to teach or suggest the invention as presently defined by independent claim 1. Therefore, reconsideration and withdrawal of the rejection of claim 1, and all claims dependent therefrom, are respectfully requested.

C. Claims 10-11 and 13-15 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kocur in view of Calcote and in further view of U.S. Patent No. 6,663,662 to Pacetti et al. (hereinafter "Pacetti"). Applicants respectfully traverse.

Pacetti is directed to a diffusion barrier for an implantable device. (Pacetti, abstract). The device includes reservoirs containing a therapeutic agent. (Pacetti, column 2, lines 52-54). The diffusion barrier reduces the rate at which a therapeutic agent is released from the device.

(Pacetti, abstract). The diffusion barrier is made from a polymeric material impregnated with particles to provide for transport of the therapeutic agent through the barrier layer. (Pacetti, column 2, lines 55-57).

Pacetti, however, fails to teach or suggest that its compositions may be used as a curable inflation medium within an inflatable channel of a graft. Indeed, Pacetti specifically teaches that its compositions are to be used as a barrier layer. (Pacetti, column 2, lines 55-57). Thus, Pacetti fails to teach or suggest that its compositions may be used within the inflatable channel of the graft as presently set forth in independent claim 1.

Further, one of ordinary skill in the art would not be motivated to combine Kocur, Calcote and Pacetti in any attempt to arrive at the present invention. For example, Calcote requires that its conduits on its graft be open C-shaped conduits or perforated conduits to allow release of a therapeutic agent toward the graft wall. (Calcote, paragraph [0024]). The use of the barrier compositions of Pacetti would seal such open portions or perforations of Calcote, thereby destroying the intent, purpose and functionality of the conduits of Calcote.

It is incumbent upon the Examiner to provide a reason why one of ordinary skill in the art would have been led to modify the specific teachings of Calcote and to combine Calcote with Kocur and Pacetti to arrive at the claimed invention. The requisite motivation for relying upon the cited references and making the proposed combination must reference some teaching, suggestion or inference in the prior art as a whole, or from the knowledge generally available to one of ordinary skill in the art and not from Applicants' disclosure. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). The only possible motivation to combine and modify these references is the teachings of the subject application. Such hindsight reconstruction, however, is strictly prohibited.

Thus, applicants respectfully submit that Kocur, Calcote and Pacetti, individually or in combination, fail to teach or suggest the invention as presently defined by independent claim 1.

Application No.: 10/769,532
Amendment and Response dated June 28, 2007
Reply to Office Action of January 29, 2007
Docket No.: 760-251 RCE II
Page 12

Therefore, reconsideration and withdrawal of the rejection of claim 1, and all claims dependent therefrom, are respectfully requested.

Thus, Kocur, Calcote, Rhee and Pacetti, individually or in combination, fail to teach or suggest the subject invention as presently defined by independent claims 1 and 21 because the references fail to teach or suggest, individually or in combination, a graft comprising, *inter alia*, the porous inflation channel as presently defined within the independent claims. Therefore, reconsideration and withdrawal of all claim rejections under 35 U.S.C. §103(a) are respectfully requested.

Further, Kocur, Calcote, Rhee and Pacetti, individually or in combination, fail to teach or suggest the subject invention as presently defined by independent claim 39 because the references fail to teach or suggest, individually or in combination, a graft comprising, *inter alia*, a curable liquid selected from the group consisting of polyethylene glycol diacrylate, ethoxylated trimethylolpropane triacrylate, or polypropylene glycol diacrylate in combination with pentaerythritol tetra 3 (mercaptopropionate).

Summary

Therefore, Applicants respectfully submit that independent claims 1, 21 and 39, and all claims dependent therefrom, are patentably distinct. This application is believed to be in condition for allowance. Favorable action thereon is therefore respectfully solicited.

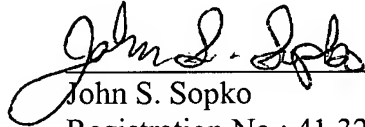
Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number given below.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if

Application No.: 10/769,532
Amendment and Response dated June 28, 2007
Reply to Office Action of January 29, 2007
Docket No.: 760-251 RCE II
Page 13

any, under 37 C.F.R § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

Respectfully submitted,



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